

Remarks

The final Office Action dated April 9, 2010, has been reviewed and following remarks are made in response thereto. Claims 1-14 are pending. Claims 1, 2, 13 and 14 are amended. Claims 15-23 are cancelled without prejudice or disclaimer to the subject matter claimed therein. Applicants submit that the amendments to the claims do not introduce any new matter. In view of the above-amendments and following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims.

Rejections under 35 U.S.C. § 103

Claims 1-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yonekawa *et al.* (JP H10-13154) ("Yonekawa") in view of Samejima *et al.* (EP 0077956) ("Samejima") (Office Action at pages 2-4). Applicants respectfully traverse this rejection for at least the reasons as set forth below.

To establish *prima facie* obviousness under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). This principle of U.S. law regarding obviousness was not altered by the recent Supreme Court holding in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007). In *KSR*, the Supreme Court stated that "Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR*, 127 S.Ct. at 1734.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1391 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.") The Court in *Graham* noted that evidence of secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, etc., "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." 383 U.S. at 18, 148 USPQ at 467. Furthermore, the Court in *KSR* took the opportunity to reiterate a second long-standing principle of U.S. law: that a holding of obviousness requires the fact finder (here, the Examiner),

to make explicit the analysis supporting a rejection under 35 U.S.C. 103, stating that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.* at 1740-41, 82 USPQ2d at 1396 (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). The Supreme Court in *KSR* stated that "a court *must* ask whether the improvement is *more than* the predictable use of prior art elements according to their established functions." *KSR* at 1740 (emphasis added). As such, in addition to showing that all elements of a claim were known in the prior art and that one of skill had a reason to combine them, the Office must also provide evidence that a reasonable expectation of success existed. MPEP 2143.02.

While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S. Ct. at 1731. The Court indicated that there is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* "Thus, in cases involving new compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda v. Alphapharm*, 492 F.3d 1350, 1357 (Fed. Cir. 2007).

The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); *see, also, In re Papesh*, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963). In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

In addition, a "combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so." Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53643, 53659 (Sep. 1, 2010) (citing *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009) (emphasis added)).

With respect to the rejection of claims 15-23, Applicants have cancelled these claims by way of this amendment, thereby rendering the rejection as to these claims moot.

With respect to the rejection of claims 1-14, without acquiescing to the merits of the Examiner's rejection, and solely to expedite prosecution of the instant claims, Applicants have amended claim 1 (from which claims 2-23 depend) to recite that the method is for treating a fluid overload state in a host and that the water-absorbent polymer is directly delivered to the intestinal tract of the host.

The Examiner asserts that by coating *Yonekawa's* composition with the enteric polymer of *Samejima*, one of ordinary skill would expect to obtain an intact and therefore effective composition for removing excess fluid from the body because without the enteric coating, the polymer in the composition (e.g. polysaccharides such as starch, carrageenan) would be more susceptible to degradation by the acidic environment of the stomach. Office Action at pages 3-4.

Applicants submit that *Yonekawa* teaches direct delivery of swellable polymers to the stomach rather than the intestinal tract. In previous Office Actions (incorporated by reference at page 2 of the current Final Office Action), the Examiner has acknowledged that *Yonekawa* does not teach direct delivery of swellable polymers to the intestinal tract. See, e.g., Non-Final Office Action mailed July 7, 2009 at page 6. In contrast to *Yonekawa*, claim 1, as amended, recites that the water-absorbent polymer is directly delivered to the intestinal tract of the host.

Samejima describes the delivery to the intestinal tract of enterically coated microcapsules that are used to deliver active core materials. *Samejima*, page 3, lines 11-16. Notably, the water-swallowable polymer of *Samejima* swells and causes the microcapsules to break open thus releasing an active agent in the intestinal tract. *Samejima*, page 4, lines 21-40. The water-swallowable polymer in the enterically coated microcapsules of *Samejima* was not used as an active agent (*Samejima*, page 12, lines 10-23), had limited absorption capacity (e.g., 1.2 to 1.5 times its weight; *id.* at page 5, line 22 to page 6, line 9), and was used only as an aid for dispersing the active agent (*id.* at page 12, lines 10-23).

Applicants submit that *Yonekawa* singly or in combination with *Samejima* fails to disclose or suggest all of the limitations of the pending claims. In particular, Applicants submit that claim 1, as amended, (from which claims 2-14 depend) is directed to a method for treating a fluid overload state by directly delivering to the intestinal tract of the host an effective amount of a water-absorbent polymer. Given that *Yonekawa* in view of *Samejima* fails to provide a

method for treating a fluid overload state by directly delivering to the intestinal tract of the host an effective amount of a water-absorbent polymer, they cannot obviate the present claims.


Applicants further submit that the Examiner has failed to set forth an objective reason for combining the teachings of the *Yonekawa* and *Samejima* and thus has not provided any motivation for enterically coating the polymers of *Yonekawa*. Nothing in *Yonekawa* or *Samejima* suggests enteric coating of the polymer of *Yonekawa* in order to directly deliver it to the intestinal tract of the host. As such, there is no reason to assume, as the Examiner has done, that enterically coating the polymer of *Yonekawa* would have been considered at the time of the instant invention.

Accordingly, for the above-mentioned reasons, Applicants respectfully request that the rejection of claims 1-23 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. The Examiner is respectfully requested to telephone the undersigned to assist in any way in expediting prosecution of this application. The Commissioner is authorized to charge any underpayment of fees or credit any overpayment of fees to Deposit Account No. 02-1818 (order no. 3716444.00011) for any matter in connection with this response.

Respectfully submitted,
K&L Gates LLP

BY 
Christopher J. Betti, Ph.D.
Reg. No. 56,890
Customer No. 24573

Dated: October 12, 2010